UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,470	10/16/2003	Warren Stern	SOHN-P01-001	8880

28120 7590 12/10/2008

ROPES & GRAY LLP
PATENT DOCKETING 39/41
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,470	STERN, WARREN	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-11 and 18* is/are pending in the application.

4a) Of the above claim(s) *7 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,6,8,9,11 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 October 2008 has been entered.

Status of Claims

Claim 1 was amended and claim 18 newly added in an amendment filed 20 October 2008. Thus, claims 1, 5-11 and 18 are pending, but claims 7 and 10 are withdrawn as being drawn to a non-elected invention. As a result, claims 1, 5, 6, 8, 9, 11 and 18 are examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 5, 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barth et al. (WO 03/097011 A1) in view of Morgan (US 5,407,953).

Applicant's claims

Applicants claim a method for reducing partial nocturnal upper airway obstruction in a patient wherein the patient does not have apnea and the obstruction does not result in hypoxemia (i.e., primary snoring) comprising administering lansoprazole.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Barth et al. teach a method of treating OSAS or obstructive sleep apnea (OSA), which is caused by a complete and/or partial obstruction of the patient's airway (a.k.a. obstructive hypopnea) (page 8, lines 9-14) by administering a therapeutically effective

amount of at least one proton pump inhibitor, such as rabeprazole, omeprazole, lansoprazole (Prevacid™), esomeprazole, pantoprazole, leminoprazole, timoprazole, tenatoprazole, disulprazole, and the like (page 13, lines 20-23; page 19, lines 8-16; page 27, lines 32-35; page 28, lines 4-7).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Barth et al. do not teach treating a patient suffering from partial nocturnal upper airway obstruction which does not result in hypoxemia. However, Morgan teaches treating sleep apnea, hypopnea and/or snoring in a human patient (Abstract). Morgan further teaches that nasopharynx obstruction is the apparent cause of obstructive sleep apnea and snoring (col. 3, ln. 24-29). Therefore, Morgan differentiates between hypopnea and snoring (i.e., snoring does not result in hypoxemia as discussed by Applicants Remarks filed 20 October 2008) and further provides motivation for treating hypopnea and/or snoring with the same medication.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to administer rabeprazole, omeprazole, lansoprazole (Prevacid™), esomeprazole, pantoprazole, leminoprazole, timoprazole, tenatoprazole, disulprazole, and the like, as taught by Barth et al., for the treatment of snoring, because Barth et al. teach these drugs for the treatment of hypopnea and Morgan teach treating apnea, hypopnea and/or snoring with the same medicament.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 12-16 that hypopnea and primary snoring differ in that hypopnea results in hypoxemia and snoring does not. Therefore, Applicants argue that since Barth et al. only teach treating patients that suffer from hypopnea, they do not anticipate treating patients that do not suffer from hypoxemia.

The examiner respectfully argues that Morgan teaches the treatment of apnea, hypopnea and/or snoring. Morgan further teaches that nasopharynx obstruction is the apparent cause of obstructive sleep apnea and snoring. Therefore, Morgan provides motivation for a person of ordinary skill in the art to treat either hypopnea or snoring with the same medicament.

2. Claims 1, 5, 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao et al. (Gastroenterology, 1998, 114(4), 336), in view of Morgan (US 5,407,953).

Applicant's claims

Applicants claim a method for reducing partial nocturnal upper airway obstruction in a patient wherein the patient does not have apnea and the obstruction does not result in hypoxemia (i.e., primary snoring) comprising administering lansoprazole.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Xiao et al. teach treating 18 patients with OSAS who suffer from snoring, daytime sleepiness and acid reflux, heartburn and regurgitation, through administration of cisapride 10 mg tid combined with omeprazole 20 mg q12h (Subject and Methods). Xiao et al. further disclose that there is a significant association between GER and esophageal body pressure, apnea/hypopnea, gross body movement, swallow and arousal (Conclusions).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Xiao et al. do not teach treating a patient suffering from partial nocturnal upper airway obstruction which does not result in hypoxemia. However, Morgan teaches treating sleep apnea, hypopnea and/or snoring in a human patient (Abstract). Morgan further teaches that nasopharynx obstruction is the apparent cause of obstructive sleep apnea and snoring (col. 3, ln. 24-29). Therefore, Morgan differentiates between hypopnea and snoring (i.e., snoring does not result in hypoxemia as discussed by Applicants Remarks filed 20 October 2008) and further provides motivation for treating hypopnea and/or snoring with the same medication.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time of the invention to administer cisapride and omeprazole, as taught by Xiao et al., for the treatment of snoring, which differs from apnea and hypopnea, because Xiao et al. teach the combination for the treatment of OSAS and Morgan teaches treating apnea, hypopnea and/or snoring with the same medicament.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 16 that GER and OSAS differ from primary snoring in that GER and OSAS result in hypoxemia and snoring does not. Therefore, Applicants argue that since Xiao et al. only teach treating patients that suffer from GER and OSAS do not anticipate treating patients that do not suffer from hypoxemia.

The examiner respectfully argues that Morgan teaches the treatment of apnea, hypopnea and/or snoring with the same medicament. Morgan further teaches that nasopharynx obstruction is the apparent cause of obstructive sleep apnea and snoring. Therefore, Morgan provides motivation for a person of ordinary skill in the art to treat either apnea, hypopnea or snoring with the same medicament.

3. Claims 1, 5, 6, 8, 9, 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiao et al. (Gastroenterology, 1998, 114(4), 336), in view of Morgan (US 5,407,953) and Hunt (Archives of Internal Medicine, 1999, 159(7), 649-657).

Applicant claims:

Applicants claim a method for reducing partial nocturnal upper airway obstruction comprising administering lansoprazole.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The teachings of Xiao et al. and Morgan are discussed above and incorporated herein by reference.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Xiao et al. and Morgan do not teach treating patients who snore (i.e., partial nocturnal upper airway obstruction) with lansoprazole. However, Hunt teaches that omeprazole, lansoprazole and pantoprazole are proton pump inhibitors (PPI's) that are effective in the treatment of GERD.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use lansoprazole in the place of omeprazole for the treatment of patients suffering from GERD and snoring, as reasonably taught by Xiao et al. One of ordinary skill in the art would have been motivated to treat a patient suffering from

partial nocturnal upper airway obstruction (i.e., snoring or hypopnea) with the PPI's because Xiao et al. teach that there is a significant relationship between GERD and hypopnea, and GERD is known to be treated with PPI's such as omeprazole and lansoprazole, as reasonably taught by Hunt.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616